

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James FULLER

Title: NUCLEIC ACID CONSTRUCTS

Appl. No.: 10/575,087

Filing Date: April 10, 2006

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MH/

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits. Therefore, no fee is due.

RELEVANCE OF EACH DOCUMENT

Documents B1-B48 were found during a search of the files of the present application and related patent applications. All documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicants believe that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Michael M. Kel
By _____
Reg. No. 34,717

Date Feb 13, 2007

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5483
Facsimile: (202) 672-5399

J.P.
Richard C. Peet
Attorney for Applicants
Registration No. 35,792

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>February 15, 2007</u> (use as many sheets as necessary)				Complete if Known	
Sheet	1	of	4	Application Number	10/575,087
				Filing Date	April 10, 2006
				First Named Inventor	James FULLER
				Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	036481-0177

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
B1	5,100,792		03/31/1992	SANFORD et al.	
B2	5,168,062		12/01/1992	STINSKI	
B3	5,385,839		01/31/1995	STINSKI	
B4	5,630,796		05/20/1997	BELLHOUSE et al.	
B5	5,865,796		02/02/1999	MCCABE	
B6	6,110,707		08/29/2000	NEWGARD et al.	
B7	6,218,140		04/17/2001	FLECKENSTEIN et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ - Kind Code ⁵ (if known)				
B8	CA 2,425,852 A		04/18/2002	CHIRON CORPORATION		
B9	EP 0323997 B1		07/19/1989	CELLTECH LIMITED		
B10	WO 95/020660		08/03/1995	UNIV. OF MASSACHUSETTS MEDICAL CENTER		
B11	WO 99/003981		01/28/1999	PPL THERAPEUTICS		
B12	WO 99/061472		12/02/1999	VALENTIS, INC.		
B13	WO 00/023592		04/27/2000	POWDERJECT VACCINES, INC.		
B14	WO 01/058483 A2		08/16/2001	THE UNIVERSITY OF VIRGINIA PATENT FOUNDATION		
B15	WO 02/031137 A2		04/18/2002	CHIRON CORPORATION		
B16	WO 02/036792 A2		05/10/2002	GLAXO GROUP LIMITED		
B17	WO 02/094313 A2		11/28/2002	POWDERJECT VACCINES, INC. and POWDERJECT RESEARCH LIMITED		
B18	WO 03/011334 A1		02/13/2003	GLAXOSMITHKLINE BIOLOGICALS S.A. and GLAXO GROUP LIMITED		
B19	WO 03/004055 A2		01/16/2003	POWDERJECT VACCINES, INC.		
B20	WO 05/035779 A2		04/21/2005	POWDERJECT VACCINES, INC.		
B21	WO 06/082398 A2		08/26/2006	POWDERJECT VACCINES, INC. and POWDERMED LIMITED		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

WASH_1809091.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MH/

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/575,087
Date Submitted: February 15, 2007 (use as many sheets as necessary)				Filing Date	April 10, 2006
				First Named Inventor	James FULLER
				Art Unit	Unassigned
				Examiner Name	Unassigned
Sheet	2	of	4	Attorney Docket Number	036481-0177

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	B22	ARRINGTON et al., "Plasmid Vectors Encoding Cholera Toxin or the Heat-Labile Enterotoxin from <i>Escherichia coli</i> Are Strong Adjuvants for DNA Vaccines," <i>Journal Of Virology</i> , May 2002, pp. 4536-4546, vol. 76, no. 9, [XP-002379962].	
	B23	BANERJI et al., "Expression of a β-Globin Gene Is Enhanced by Remote SV40 DNA Sequences," <i>Cell</i> , Dec. 1981 (Part 1), pp. 299-208, vol. 27.	
	B24	BARDIYA et al., "Influenza Vaccines: Recent Advances in Production Technologies," <i>Appl Microbiol Biotechnol</i> , 2005, pp. 299-305, vol. 67, no. 3 [XP-002379964].	
	B25	CHAN et al., "Synergistic Interactions between Overlapping Binding Sites for the Serum Response Factor and ELK-1 Proteins Mediate both Basal Enhancement and Phorbol Ester Responsiveness of Primate Cytomegalovirus Major Immediate-Early Promoters in Monocyte and T-Lymphocyte Cell Types," <i>Journal Of Virology</i> , Dec. 1996, pp. 8590-8605, vol. 70, no. 12 [XP-002331463].	
	B26	CHAPMAN et al., "Effect of Intron A from Human Cytomegalovirus (Towne) Immediate-Early Gene on Heterologous Expression in Mammalian Cells," <i>Nucleic Acids Research</i> , 1991, pp. 3979-3986, vol. 19, no. 14, Oxford University Press.	
	B27	devILLIERS et al., "A Small Segment of Polyoma Virus DNA Enhances the Expression of a Cloned β-Globin Gene over a Distance of 1400 Base Pairs," <i>Nucleic Acids Research</i> , 1981, pp. 6251-6264, vol. 9, no. 23.	
	B28	DONNELLY et al., "Preclinical Efficacy of a Prototype DNA Vaccine: Enhanced Protection Against Antigenic Drift in Influenza Virus," <i>Nature Medicine</i> , June 1995, pp. 583-587, vol. 1, no. 6 [XP 000508527].	
	B29	FULLER et al., "Immune Responses to Hepatitis B Virus Surface and Core Antigens in Mice, Monkeys, and Pigs after Accell® Particle-Mediated DNA Immunization," <i>Annals New York Academy of Sciences</i> , 1995, pp. 282-284, vol. 772, no. 27 [XP-000891484].	
	B30	GARMORY et al., "DNA Vaccines: Improving Expression of Antigens," <i>Genetic Vaccines and Therapy</i> , 2003, pp. 1-5, vol. 1, no. 2 [XP-002379963].	
	B31	HAENSLER et al., "Intradermal DNA Immunization by Using Jet-Injections in Mice and Monkeys," <i>Vaccine</i> , 1999, pp. 628-638, vol. 17, nos. 7-8.	
	B32	HEARING et al., "The Adenovirus Type 5 E1A Transcriptional Control Region Contains a Duplicated Enhancer Element," <i>Cell</i> , July 1983, pp. 695-703, vol. 33.	
	B33	KUTINOVA et al., "Hepatitis B virus proteins expressed by recombinant vaccinia viruses: influence of preS2 sequence on expression surface and nucleocapsid proteins in human diploid cells," <i>Archives of Virology</i> , 1994, pp. 1-15, vol. 134.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

WASH_1809091.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MH/

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/575,087
Date Submitted: <u>February 15, 2007</u>				Filing Date	April 10, 2006
(use as many sheets as necessary)				First Named Inventor	James FULLER
Sheet	3	of	4	Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	036481-0177

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁸
	B34	LEE et al., "Development of a Polynucleotide Vaccine from Melanoma Antigen Recognized by T Cells-1 and Recombinant Protein from Melanoma Antigen Recognized by T Cells-1 for Melanoma Vaccine Clinical Trials," <u>Journal of Immunotherapy</u> , 2000, pp. 379-386, vol. 23, no. 3.	
	B35	LEVINSON et al., "Activation of SV40 genome by 72-base pair tandem repeats of Moloney sarcoma virus," <u>Nature</u> , Feb. 1982, pp. 568-5721, vol. 295.	
	B36	LÖSER et al., "Evaluation of HBV Promoters for Use in Hepatic Gene Therapy," <u>Biol Chem.</u> , Mar. 1996, pp. 187-193, vol. 377.	
	B37	LUCIW et al., "Location and Function of Retroviral and SV40 Sequences That Enhance Biochemical Transformation after Microinjection of DNA," <u>Cell</u> , Jul. 1983, pp. 705-716, vol. 33.	
	B38	MASUDA et al., "Effect of the PreS1 RNA Sequence on the Efficiency of the Hepatitis B Virus PreS2 and S Protein Translation," <u>Virology</u> , 1990, pp. 320-324, vol. 174.	
	B39	MONTGOMERY et al., "Heterologous and Homologous Protection Against Influenza A by DNA Vaccination: Optimization of DNA Vectors," <u>DNA And Cell Biology</u> , 1993, pp. 777-783, vol. 12, no. 9 [XP 000565708].	
	B40	ROSENTHAL et al., "BK Viral Enhancer Element and a Human Cellular Homolog," <u>Science</u> , 1983, pp. 749-755, vol. 222.	
	B41	ROTONDARO et al., "Efficiency of different viral promoters in directing gene expression in mammalian cells: effect of 3'-untranslated sequences," <u>Gene</u> , 1996, pp. 195-198, vol. 168, no. 2.	
	B42	ROY et al., "Induction of antigen-specific CD8 + T cells, T helper cells, and protective levels of antibody in humans by particle-mediated administration of a hepatitis B virus DNA vaccine," <u>Vaccine</u> , 2001, pp. 764-778, vol. 19.	
	B43	SIMARI et al., "Improved transgene expression in vascular smooth muscle cells using downstream sequences from the CMV IE gene," <u>Circulation</u> , Supplement 1, Oct. 15, 1996, p. 1-44, vol. 94, no. 8.	
	B44	SIMONSEN et al., "Analysis of Processing and Polyadenylation Signals of the Hepatitis B Virus Surface Antigen Gene by Using Simian Virus 40-Hepatitis B Virus Chimeric Plasmids," <u>Molecular And Cellular Biology</u> , Dec. 1983, pp. 2250-2258, vol. 3, no. 12.	
	B45	WASENAUER et al., "A Cysteine and a Hydrophobic Sequence in the Noncleaved Portion of the Pre-C Leader Peptide Determine the Biophysical Properties of the Secretary Core Protein (HBe Protein) of Human hepatitis B Virus," <u>Journal Of Virology</u> , Sep. 1992, pp. 5338-5346, vol. 66, no. 9 [XP-002977293].	
	B46	WEEKS et al., "E1A Control of Gene Expression Is Mediated by Sequences 5' to the Transcriptional Starts of the Early Viral Genes," <u>Molecular And Cellular Biology</u> , Jul. 1983, pp. 1222-1234, vol. 3.	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/575,087
Date Submitted: <u>February 15, 2007</u>				Filing Date	April 10, 2006
(use as many sheets as necessary)				First Named Inventor	James FULLER
Sheet	4	of	4	Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	036481-0177

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ⁶
	B47	YANG et al., "Particle Bombardment Technology for Gene Transfer (1994)," Oxford University Press, New York, NY, 1994, pp. 10-11.		
	B48	ZINCKGRAF et al., "Modulating gene expression using DNA vaccines with different 3'-UTRs influences antibody titer, seroconversion and cytokine profiles," <u>Vaccine</u> , 2003, pp. 1640-1649, vol. 21, no. 15.		

Examiner Signature	/Michelle Horning/	Date Considered	09/07/2010
--------------------	--------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.
WASH_1809091.1 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MH/